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(54) **Intravascular filtering device**

Intravaskuläre Filtereinrichtung

Dispositif de filtrage intravasculaire

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(56) References cited:
DE-B- 2 821 048 **US-A- 4 425 908**
US-A- 4 619 246 **US-A- 4 832 055**

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Description

[0001] The present invention generally relates to intravascular devices for treating certain medical conditions.

[0002] The devices made in accordance with the invention are particularly well suited for delivery through a catheter or the like to a remote location in a patient's vascular system or in analogous vessels within a patient's body.

[0003] A wide variety of intravascular devices are used in various medical procedures. Certain intravascular devices, such as catheters and guidewires, are generally used simply to deliver fluids or other medical devices to specific locations within a patient's body, such as a selective site within the vascular system. Other, frequently more complex, devices are used in treating specific conditions, such as devices used in removing vascular occlusions or for treating septal defects and the like.

[0004] In certain circumstances, it may be necessary to occlude a patient's vessel, such as to stop blood flow through an artery to a tumor or other lesion. Presently, this is commonly accomplished simply by inserting, e.g. Ivalon particles, a trade name for vascular occlusion particles, and short sections of coil springs into a vessel at a desired location. These "embolization agents" will eventually become lodged in the vessel, frequently floating downstream of the site at which they are released before blocking the vessel. In part due to the inability to precisely position the embolization agents, this procedure is often limited in its utility.

[0005] Detachable balloon catheters are also used to block patients' vessels. When using such a catheter, an expandable balloon is carried on a distal end of a catheter. When the catheter is guided to the desired location, the balloon is filled with a fluid until it substantially fills the vessel and becomes lodged therein. Resins which will harden inside the balloon, such as an acrylonitrile, can be employed to permanently fix the size and shape of the balloon. The balloon can then be detached from the end of the catheter and left in place.

[0006] Such balloon embolizations are also prone to certain safety problems, though. For example, if the balloon is not filled enough, it will not be firmly fixed in the vessel and may drift downstream within the vessel to another location, much like the loose embolization agents noted above. In order to avoid this problem, physicians may overfill the balloons; it is not uncommon for balloons to rupture and release the resin into the patient's bloodstream.

[0007] In still other procedures, it may not be necessary to permanently occlude a vessel, but it may be necessary to provide a filter or the like to prevent thrombi from passing a particular location. For example, rotating burrs are used in removing atheroma from the lumen of patients' blood vessels. These burrs can effectively dislodge the atheroma, but the dislodged material will sim-

ply float downstream with the flow of blood through the vessel unless steps are taken to capture the material.

[0008] Some researchers have proposed various traps or filters for capturing the particulate matter released or created in such procedures. However, such filters generally have not proven to be exceptionally effective in actual use. Such filters tend to be cumbersome to use and accurate deployment is problematic because if they are not properly seated in the vessel they can drift to a more distal site where they are likely to do more harm than good. In addition, these filters are generally capable of only trapping relatively large thrombi and are not effective means for removing smaller embolic particles from the blood stream.

[0009] The problems with temporary filters, which are intended to be used only during a particular procedure then retracted with the thrombi trapped therein, are more pronounced. Even if the trap does effectively capture the dislodged material, it has proven to be relatively difficult or complex to retract the trap back into the catheter through which it was delivered without simply dumping the trapped thrombi back into the blood stream, defeating the purpose of the temporary filter device. For this reason, most atherectomy devices and the like tend to aspirate the patient's blood during the procedure to remove the dislodged material entrained therein.

[0010] Mechanical embolization devices, filters and traps have been proposed in the past. Even if some of those devices have proven effective, they tend to be rather expensive and time-consuming to manufacture. For example, some intravascular blood filters suggested by others are formed of a plurality of specially-shaped legs which are adapted to fill the vessel and dig into the vessel walls. In making most such filters, the legs must be individually formed and then painstakingly attached to one another, frequently entirely by hand, to assemble the final filter. Not only does this take significant skilled manpower, and hence increase the costs of such devices, the fact that each item must be made by hand tends to make quality control more difficult. This same difficulty and expense of manufacturing is not limited to such filters, but is experienced in many other intravascular devices as well.

[0011] US 4,832,055 describes a blood clot filter formed of overlapping loops of wire which is designed to be placed permanently in a blood vessel.

[0012] Accordingly, it would be desirable to provide devices for deployment in a vessel in a patient's vessel which are both economical to make and can be consistent and reproducible. It would also be advantageous to provide a reliable embolization device which is both easy to deploy and can be accurately placed in a vessel. Furthermore, there is a need in the art for a trap or filter which can be deployed within a vessel for capturing thrombi, which trap can be reliably deployed; if the trap is to be used only temporarily, it should be readily withdrawn from the patient without simply dumping the

trapped thrombi back into the blood stream.

[0013] The present invention provides a trap for trapping particulate material entrained in a fluid within a channel of a patient's body, comprising a guidewire having a distal end and a basket carried by the guidewire adjacent the distal end, the basket being adapted to strain the particulate material from fluid passing there-through and comprising a metal fabric having first and second ends, at least one end of the fabric being adapted to slide along the guidewire, the metal fabric having a collapsed configuration wherein the first and second ends are spaced from one another a first distance along the guidewire and the metal fabric has a first diameter, and an expanded configuration wherein the first and second ends are spaced a second, shorter distance along the guidewire and the metal fabric has a second diameter, the first diameter being less than the second diameter.

[0014] A metal fabric may be formed of a plurality of resilient strands, with the wires preferably being formed of a resilient material which can be heat treated to substantially set a desired shape. This fabric may be deformed to generally conform to a molding surface of a molding element and the fabric is heat treated in contact with the surface of the molding element at an elevated temperature. The time and temperature of the heat treatment is selected to substantially set the fabric in its deformed state. After the heat treatment, the fabric can be removed from contact with the molding element and will substantially retain its shape in the deformed state. The fabric so treated defines an expanded state of a medical device which can be deployed through a catheter into a channel in a patient's body.

[0015] The distal end of a catheter can be positioned in a channel in a patient's body to position the distal end of the catheter adjacent a treatment site for treating a physiological condition. A medical device made in accordance with the process outlined above can be collapsed and inserted into the lumen of the catheter. The device is urged through the catheter and out the distal end, whereupon it will tend to return to its expanded state adjacent the treatment site.

[0016] The invention will now be illustrated with reference to the accompanying drawings, in which:

Figures 1A and 1B each depict a metal fabric suitable for use with the invention;

Figures 2A and 2B are a side view and a perspective view, respectively, of a molding element and a length of metal fabric suitable for use in forming a medical device similar to that the invention, the mold being in a disassembled state;

Figure 3A is a perspective view showing the molding element and metal fabric of Figure 2 in a partially assembled state;

Figure 3B is a close-up view of the highlighted area of Figure 3A showing the compression of the metal fabric in the molding element;

Figure 4 is a cross-sectional view showing the molding element and metal fabric of Figure 2 in an assembled state;

Figure 5A is a schematic side view of yet another medical device made in accordance with the invention showing the device in a collapsed state for deployment in a patient's vascular system;

Figure 5B is a schematic side view of the medical device of Figure 5A in an expanded state for deployment in a patient's vascular system;

Figure 6A is a schematic side view of an alternative embodiment of the invention of Figure 5A showing the device in a collapsed state within a catheter for deployment;

Figure 6B is a schematic side view of the device of Figure 6A showing the device deployed distally of the catheter;

Figure 7 is a schematic perspective view showing a medical device in accordance with yet a further embodiment of the invention collapsed within a catheter for deployment in a channel in a patient's body;

Figure 8 is a schematic side view of the device of Figure 7 in a partially deployed state;

Figure 9 is a schematic side view of the device of Figure 7 in a fully deployed state; and

Figure 10 illustrated a moulding element for use in making devices according to the invention.

[0017] The present invention provides devices for use in channels in patients' bodies, such as vascular channels, urinary tracts, biliary ducts and the like. In a method for forming a medical device of the invention a metal fabric 10 is provided. The fabric is formed of a plurality of wire strands having a predetermined relative orientation between the strands. Figures 1A and 1B illustrate two examples of metal fabrics which are suitable for use in the invention.

[0018] In the fabric of Figure 1A, the metal strands define two sets of essentially parallel generally helical strands, with the strands of one set having a "hand", i.e. a direction of rotation, opposite that of the other set. This defines a generally tubular fabric, known in the fabric industry as a tubular braid. Such tubular braids are well known in the fabric arts and find some applications in the medical device field as tubular fabrics, such as in reinforcing the wall of a guiding catheter. As such braids are well known, they need not be discussed at length here.

[0019] The pitch of the wire strands (i.e. the angle defined between the turns of the wire and the axis of the braid) and the pick of the fabric (i.e. the number of turns per unit length) may be adjusted as desired for a particular application. For example, if a medical device to be formed is to be used to occlude the channel in which it is placed, the pitch and pick of the fabric will tend to be higher than if the device is simply intended to filter bodily fluid passing therethrough.

[0020] Figure 1B illustrates another type of fabric which is suitable for use in the invention. This fabric is a more conventional fabric and may take the form of a flat woven sheet, knitted sheet or the like. In the woven fabric shown in Figure 1B, there are also two sets 14 and 14' of generally parallel strands, with one set of strands being oriented at an angle, e.g. generally perpendicular (having a pick of about 90°), with respect to the other set. As noted above, the pitch and pick of this fabric (or, in the case of a knit fabric, the pick and the pattern of the knit, e.g. Jersey or double knits) may be selected to optimize the desired properties of the final medical device.

[0021] The wire strands of the metal fabric used are preferably formed of a material which is both resilient and can be heat treated to substantially set a desired shape. Materials which are believed to be suitable for this purpose include a cobalt-based low thermal expansion alloy referred to in the field as Elgiloy, nickel-based high-temperature high-strength "superalloys" commercially available from Haynes International under the trade name Hastelloy, nickel-based heat treatable alloys sold under the name Incoloy by International Nickel, and a number of different grades of stainless steel. The important factor in choosing a suitable material for the wires is that the wires retain a suitable amount of the deformation induced by the molding surface (as described below) when subjected to a predetermined heat treatment.

[0022] One class of materials which meet these qualifications are so-called shape memory alloys. Such alloys tend to have a temperature induced phase change which will cause the material to have a preferred configuration which can be fixed by heating the material above a certain transition temperature to induce a change in the phase of the material. When the alloy is cooled back down, the alloy will "remember" the shape it was in during the heat treatment and will tend to assume that configuration unless constrained from so doing.

[0023] One particularly preferred shape memory alloy for use is nitinol, an approximately stoichiometric alloy of nickel and titanium, which may also include other minor amounts of other metals to achieve desired properties. NiTi alloys such as nitinol, including appropriate compositions and handling requirements, are well known in the art and such alloys need not be discussed in detail here. For example, U.S. Patents 5,067,489 (Lind) and 4,991,602 (Amplatz et al.) discuss the use of shape memory NiTi alloys in guidewires. Such NiTi alloys are preferred, at least in part, because they are commercially available and more is known about handling such alloys than other known shape memory alloys. NiTi alloys are also very elastic - they are said to be "superelastic" or "pseudoelastic". This elasticity will help a device of the invention return to a present expanded configuration for deployment.

[0024] The wire strands can comprise a standard

monofilament of the selected material, i.e. a standard wire stock may be used. If so desired, though, the individual wire strands may be formed from "cables" made up of a plurality of individual wires. For example, cables formed of metal wires where several wires are helically wrapped about a central wire are commercially available and NiTi cables having an outer diameter of 0.003 inch (approx 0.076 mm) or less can be purchased. One advantage of certain cables is that they tend to be "softer" than monofilament wires having the same diameter and formed of the same material. Additionally, if the device being formed from the wire strands is to be used to occlude a vessel, the use of a cable can increase the effective surface area of the wire strand, which will tend to promote thrombosis.

[0025] In preparation of forming a medical device in keeping with the invention, an appropriately sized piece of the metal fabric is cut from the larger piece of fabric which is formed, for example, by braiding wire strands to form a long tubular braid. The dimensions of the piece of fabric to be cut will depend, in large part, upon the size and shape of the medical device to be formed therefrom.

[0026] When cutting the fabric to the desired dimensions, care should be taken to ensure that the fabric will not unravel. In the case of tubular braids formed of NiTi alloys, for example, the individual wire strands will tend to return to their heat-set configuration unless constrained. If the braid is heat treated to set the strands in the braided configuration, they will tend to remain in the braided form and only the ends will become frayed. However, it may be more economical to simply form the braid without heat treating the braid since the fabric will be heat treated again in forming the medical device, as noted below.

[0027] In such untreated NiTi fabrics, the strands will tend to return to their unbraided configuration and the braid can unravel fairly quickly unless the ends of the length of braid cut to form the device are constrained relative to one another. One method which has proven to be useful to prevent the braid from unraveling is to clamp the braid at two locations and cut the braid to leave a length of the braid having clamps (15 in Figure 2) at either end, thereby effectively defining an empty space within a sealed length of fabric. These clamps 15 will hold the ends of the cut braid together and prevent the braid from unraveling.

[0028] Alternatively, one can solder, braze, weld or otherwise affix the ends of the desired length together (e.g. with a biocompatible cementitious organic material) before cutting the braid. Although soldering and brazing of NiTi alloys has proven to be fairly difficult, the ends can be welded together, such as by spot welding with a laser welder.

[0029] The same problems present themselves when a flat sheet of fabric such as the woven fabric shown in Figure 1B is used. With such a fabric, the fabric can be inverted upon itself to form a recess or depression and

the fabric can be clamped about this recess to form an empty pocket (not shown) before the fabric is cut. If it is desired to keep the fabric in a generally flat configuration, it may be necessary to weld the junctions of the strands together adjacent the periphery of the desired piece of fabric before that piece is cut from the larger sheet. So connecting the ends of the strands together will prevent fabrics formed of untreated shape memory alloys and the like from unraveling during the forming process.

[0030] Once an appropriately sized piece of the metal fabric is obtained, the fabric is deformed to generally conform to a surface of a molding element. As will be appreciated more fully from the discussion below in connection with Figures 2-16, so deforming the fabric will reorient the relative positions of the strands of the metal fabric from their initial order to a second, reoriented configuration. The shape of the molding element should be selected to deform the fabric into substantially the shape of the desired medical device.

[0031] The molding element can be a single piece, or it can be formed of a series of mold pieces which together define the surface to which the fabric will generally conform. The molding element can be positioned within a space enclosed by the fabric or can be external of such a space, or can even be both inside and outside such a space.

[0032] In order to illustrate one example of how such a mold may be configured and how it may be used reference will be had to Figures 2-5. In Figures 2-4, the molding element 20 is formed of a number of separate pieces which can be attached to one another to complete the molding element 20. In using such a multi-piece molding element, the mold can be assembled about the cut length of fabric 10, thereby deforming the fabric to generally conform to the desired surface (or surfaces) of the molding element.

[0033] In the molding element illustrated in Figures 2-4, the metal fabric 10 is deformed to generally conform to a surface of the molding element 20, the molding element comprising a center section 30 and a pair of end plates 40. Turning first to the center section 30, the center section is desirably formed of opposed halves 32, 32 which can be moved away from one another in order to introduce the metal fabric 10 into the mold. Although these two halves 32, 32 are shown in the drawings as being completely separated from one another, it is to be understood that these halves could be interconnected, such as by means of a hinge or the like, if so desired. The opposed halves of the molding element 20 shown in the drawings of Figures 2 and 3 each include a pair of semi-circular recesses opposed on either side of a ridge defining a generally semi-circular opening. When the two halves are assembled in forming the device, as best seen in Figure 3, the semi-circular openings in the opposed halves 32, 32 mate to define a generally circular forming port 36 passing through the center section 30. Similarly, the semi-circular recesses in the two

halves together form a pair of generally circular central recesses 34, with one such recess being disposed on either face of the center section.

[0034] The overall shape and dimensions of the center section can be varied as desired; it is generally the size of the central recesses 34 and the forming port 36 which will define the size and shape of the middle of the finished device, as explained below. If so desired, each half 32 may be provided with a manually graspable projection 38. In the embodiment shown in the drawings, this projection 38 is provided at a location disposed away from the abutting faces of the respective halves. Such a manually graspable projection 38 will simply enable an operator to more easily join the two halves to define the recesses 34 and forming port 36.

[0035] The center section is adapted to cooperatively engage a pair of end plates 40 for forming the desired device. In the embodiment shown in Figures 2 and 3, the center section 30 has a pair of flat outer faces 39 which are each adapted to be engaged by an inner face 42 of one of the two end plates 40. Each end plate includes a compression disk 44 which extends generally laterally inwardly from the inner face 42 of the end plate. This compression disk 44 should be sized to permit it to be received within one of the central recesses 34 on either face of the center section 30. For reasons explained more fully below, each compression disk 44 includes a cavity 46 for receiving an end of the length of the metal fabric 10.

[0036] One or more channels 48 for receiving bolts and the like may also be provided through each of the end plates and through the center section 30. By passing bolts through these channels 48, one can assemble the molding element 20 and retain the metal fabric in the desired shape during the heat treatment process, as outlined below.

[0037] In utilizing the molding element 20 shown in Figures 2-4, a length of the metal fabric 10 can be positioned between the opposed halves 32 of the center section 30. In the drawings of the molding element 20 of Figures 2-4, the metal fabric 10 is a tubular braid such as that illustrated in Figure 1A. A sufficient length of the tubular braid should be provided to permit the fabric to conform to the molding surface, as explained below. Also, as noted above, care should be taken to secure the ends of the wire strands defining the tubular braid in order to prevent the metal fabric from unraveling.

[0038] A central portion of the length of the metal braid may be positioned within one of the two halves of the forming port 36 and the opposed halves 32 of the center section may be joined to abut one another to restrain a central portion of the metal braid within the central forming port 36 through the center section.

[0039] The tubular braid will tend to have a natural, relaxed diameter which is defined, in large part, when the tubular braid is formed. Unless the tubular braid is otherwise deformed, when the wire strands are in their relaxed state they will tend to define a generally hollow

tube having the predetermined diameter. The outer diameter of the relaxed braid may be, for example, about 4 mm. The relative size of the forming port 36 in the central section 30 of the molding element and the natural, relaxed outer diameter of the tubular braid may be varied as desired to achieve the desired shape of the medical device being formed.

[0040] In the embodiment shown in Figures 2 and 3, the inner diameter of the forming port 36 is optimally slightly less than the natural, relaxed outer diameter of the tubular braid 10. Hence, when the two halves 32, 32 are assembled to form the center section 30, the tubular braid 10 will be slightly compressed within the forming port 36. This will help ensure that the tubular braid conforms to the inner surface of the forming port 36, which defines a portion of the molding surface of the molding element 20.

[0041] If so desired, a generally cylindrical internal molding section (not shown) may also be provided. This internal molding section has a slightly smaller diameter than the inner diameter of the forming port 36. In use, the internal molding section is placed within the length of the metal fabric, such as by manually moving the wire strands of the fabric apart to form an opening through which the internal molding section can be passed. This internal molding section should be positioned within the tubular braid at a location where it will be disposed within the forming port 36 of the center section when the molding element is assembled. There should be a sufficient space between the outer surface of the interior molding section and the inner surface of the forming port 36 to permit the wire strands of the fabric 10 to be received therebetween.

[0042] By using such an internal molding section, the dimensions of the central portion of the finished medical device can be fairly accurately controlled. Such an internal molding section may be necessary in circumstances where the natural, relaxed outer diameter of the tubular braid 10 is less than the inner diameter of the forming port 36 to ensure that the braid conforms to the inner surface of that forming port. However, it is not believed that such an internal molding section would be necessary if the natural, relaxed outer diameter of the braid were larger than the inner diameter of the forming port 36.

[0043] As noted above, the ends of the tubular braid should be secured in order to prevent the braid from unraveling. Each end of the metal fabric 10 is desirably received within a cavity 46 formed in one of the two end plates 40. If a clamp (15 in Figures) is used, the clamp may be sized to be relatively snugly received within one of these cavities 46 in order to effectively attach the end of the fabric to the end plate 40. The end plates can then be urged toward the center section 30 and toward one another until the compression disk 44 of each end plate is received within a central recess 34 of the center section 30. The molding element may then be clamped in position by passing bolts or the like through the channels

48 in the molding element and locking the various components of the molding element together by tightening a nut down onto such a bolt (not shown).

[0044] As best seen in Figure 3A, when an end plate is urged toward the center section 30, this will compress the tubular braid 10 generally along its axis. When the tubular braid is in its relaxed configuration, as illustrated in Figure 1A, the wire strands forming the tubular braid will have a first, predetermined relative orientation with respect to one another. As the tubular braid is compressed along its axis, the fabric will tend to flare out away from the axis, as illustrated in Figure 4. When the fabric is so deformed, the relative orientation of the wire strands of the metal fabric will change. When the molding element is finally assembled, the metal fabric will generally conform to the molding surface of this element.

[0045] In the molding element 20 shown in Figures 2-4, the molding surface is defined by the inner surface of the forming port, the inner surfaces of the central recess 34 and the faces of the compression disks 44 which are received within the recesses 34. If an internal molding section is used, the cylindrical outer surface of that section may also be considered a part of the molding surface of the molding element 20. Accordingly, when the molding element 20 is completely assembled the metal fabric will tend to assume a somewhat "dumbbell"-shaped configuration, with a relatively narrow center section disposed between a pair of bulbous, perhaps even disk-shaped end sections, as best seen in Figure 4.

[0046] It should be understood that the specific shape of the particular molding element 20 shown in Figures 2-4 is intended to produce one useful medical device in accordance with the present method, but that other molding elements having different configurations could also be used. If a more complex shape is desired, the molding element may have more parts, but if a simpler shape is being formed the molding element may have even fewer parts. The number of parts in a given molding element and the shapes of those parts will be dictated almost entirely by the shape of the desired medical device as the molding element must define a molding surface to which the metal fabric will generally conform.

[0047] Accordingly, the specific molding element 20 shown in Figures 2-4 is simply intended as one specific example of a suitable molding element for forming one particular useful medical device. Additional molding elements having different designs for producing different medical devices are explained below in connection with, e.g., Figures 8 and 10. Depending on the desired shape of the medical device being formed, the shape and configuration of other specific molding elements can be readily designed by those of ordinary skill in the art.

[0048] Once the molding element 20 is assembled with the metal fabric generally conforming to a molding surface of that element, the fabric can be subjected to a heat treatment while it remains in contact with that

molding surface. This heat treatment will depend in large part upon the material of which the wire strands of the metal fabric are formed, but the time and temperature of the heat treatment should be selected to substantially set the fabric in its deformed state, i.e., wherein the wire strands are in their reoriented relative configuration and the fabric generally conforms to the molding surface.

[0049] The time and temperature of the heat treatment can vary greatly depending upon the material used in forming the wire strands. As noted above, one preferred class of materials for forming the wire strands are shape memory alloys, with nitinol, a nickel titanium alloy, being particularly preferred. If nitinol is used in making the wire strands of the fabric, the wire strands will tend to be very elastic when the metal is in its austenitic phase; this very elastic phase is frequently referred to as a "superelastic" or "pseudoelastic" phase. By heating the nitinol above a certain phase transition temperature, the crystal structure of the nitinol metal when in its austenitic phase can be set. This will tend to "set" the shape of the fabric and the relative configuration of the wire strands in the positions in which they are held during the heat treatment.

[0050] Suitable heat treatments of nitinol wire to set a desired shape are well known in the art. Spirally wound nitinol coils, for example, are used in a number of medical applications, such as in forming the coils commonly carried around distal lengths of guidewires. A wide body of knowledge exists for forming nitinol in such medical devices, so there is no need to go into great detail here on the parameters of a heat treatment for the nitinol fabric preferred for use in the present invention.

[0051] Briefly, though, it has been found that holding a nitinol fabric at about 500°C to about 550°C for a period of about 1 to about 30 minutes, depending on the softness or hardness of the device to be made, will tend to set the fabric in its deformed state, i.e. wherein it conforms to the molding surface of the molding element. At lower temperatures the heat treatment time will tend to be greater (e.g. about one hour at about 350°C) and at higher temperatures the time will tend to be shorter (e.g. about 30 seconds at about 900°C). These parameters can be varied as necessary to accommodate variations in the exact composition of the nitinol, prior heat treatment of the nitinol, the desired properties of the nitinol in the finished article, and other factors which will be well known to those skilled in this field.

[0052] Instead of relying on convection heating or the like, it is also known in the art to apply an electrical current to the nitinol to heat it. This can be accomplished by, for example, hooking electrodes to the clamps 15 carried at either end of the metal fabric illustrated in Figure 2. The wire can then be heated by resistance heating of the wires in order to achieve the desired heat treatment, which will tend to eliminate the need to heat the entire molding element to the desired heat treating temperature in order to heat the metal fabric to the desired

temperature.

[0053] After the heat treatment, the fabric is removed from contact with the molding element and will substantially retain its shape in a deformed state. When the molding element 20 illustrated in Figures 2-4 is used, the bolts (not shown) may be removed and the various parts of the molding element may be disassembled in essentially the reverse of the process of assembling the molding element. If an internal molding section is used, this molding section can be removed in much the same fashion that it is placed within the generally tubular metal fabric in assembling the molding element 20, as, detailed above.

[0054] Figures 5 and 6 illustrate alternative embodiments of a medical device in accordance with this invention. Both Figure 5 and Figure 6 illustrate a vascular trap suitable for use in temporarily filtering embolic particles from blood passing through a patient's vascular system. Such a device will most frequently be used to filter emboli from a patient's blood when another medical procedure is being performed, such as by using the trap in conjunction with a rotating cutting blade during an atherectomy or with a balloon catheter during angioplasty. It is to be understood, though, that the trap could also be used in other similar applications, such as in channels in patients' bodies other than their vascular systems.

[0055] In the embodiment of Figures 5A and 5B, the vascular trap 250 comprises a generally umbrella-shaped basket 270 carried adjacent a distal end of a guidewire 260. The guidewire in this embodiment includes a tapered distal section 262 with a spirally wound coil 264 extending along a distal length of the wire. Guidewires having such a distal end are conventional in the art. The basket 270 is positioned generally distally of the coil 264, and is desirably attached to the guidewire proximally of the proximal end of the tapered section, as shown.

[0056] The basket 270 (shown in its collapsed configuration in Figure 5A) includes a distal band 272 and a proximal band 274. The distal band may be made of a radiopaque material, such as gold, platinum or tungsten, and is affixed directly to the shaft of the guidewire 260. This attachment may be made by any suitable means, such as by welding, brazing or soldering. Alternatively, the distal band 272 may comprise a bead of a biocompatible cementitious material, such as a curable organic resin. If it is desired to increase the visibility of the band for fluoroscopic observation, a radiopaque metal or the like can be imbedded in the cementitious material. The proximal band 274 may be formed of a hypotube sized to permit the tube to slide along the guidewire during deployment. This hypotube may be made of a metallic material; a thin-walled tube of a NiTi alloy should suffice. If so desired, the proximal band may be formed of a more radiopaque metal, or a NiTi alloy band can have a radiopaque coating applied to its surface.

[0057] The body of the device is formed of a metal

fabric, as explained above. The metal fabric of this embodiment is optimally initially formed as a tubular braid and the ends of the wires forming the braid can be attached together by means of the bands 272, 274 before the fabric is cut to length. Much like the clamps 15, 90 noted above, these bands 272, 274 will help prevent the metal fabric from unravelling during the forming process. (The method of forming the basket 270 is described below in connection with Figure 10.)

[0058] When the device is in its collapsed state for deployment in a patient's vessel (as illustrated in Figure 5A), the basket 270 will be collapsed toward the axis of the guidewire 260. The distal 272 and proximal 274 bands are spaced away from one another along the length of the guidewire, with the fabric of the device extending therebetween. In a preferred embodiment, when the basket is in its collapsed state it will engage the outer surface of the guidewire to permit the device to be deployed through a relatively small lumen of a catheter or another medical device.

[0059] When the device is deployed in a patient's vascular system, the basket will take on an expanded configuration wherein it extends outwardly of the outer surface of the guidewire. As best seen in Figure 5B, the shape of the basket 270 when deployed may generally resemble a conventional umbrella or parachute, having a dome-like structure curving radially outwardly from the guidewire moving proximally from the distal band 272. It is to be understood that other suitable shapes could easily perform the desired filtering function, such as a conical shape wherein the slope of the device changes more linearly than the smooth, rounded version shown in Figure 5B. It is also believed that a relatively flat, disc shape would also suffice. In this expanded configuration, the two bands 272, 274 are closer together, with the distal band 272 optimally being spaced only a short distance from the proximal band 274, as illustrated.

[0060] In moving from its collapsed state (Figure 5A) to its expanded state (Figure 5B), the metal fabric turns in on itself, with a proximal portion 282 of the collapsed basket being received within the interior of a distal portion 284 of the collapsed basket. This produces a two-layered structure having a proximal lip 286 spaced radially outwardly of the guidewire, defining a proximally-facing cup-shaped cavity 288 of the basket. When blood (or any other fluid) flows through the basket in a distal direction, any particulate matter in the blood, e.g. emboli released into the bloodstream during atherectomy or angioplasty procedures, will tend to be trapped in the cavity 288 of the basket.

[0061] The precise dimensions of the metal fabric can be varied as desired for various applications. If the device 250 is to be used as a vascular filter to trap emboli released into the blood, for example, the pores (i.e. the openings between the crossing metal strands) of the fabric are desirably on the order of about 1.0 mm. This is generally deemed to be the minimum size of any particles which are likely to cause any adverse side effects

if they are allowed to float freely within a blood vessel. One would not want to make the pores too small, though, because the blood (or other fluid) should be free to pass through the wall of the basket 270. If so desired, the basket may be coated with a suitable anti-thrombogenic coating to prevent the basket from occluding a blood vessel in which it is deployed.

[0062] When a fabric having 1.0 mm pores is used to form the basket 270 of this embodiment of the invention, the forming process will reorient the wires relative to one another and in some areas (e.g. adjacent the proximal lip 286) the pores will be larger than 1.0 mm. However, because the basket's walls are formed of essentially two thicknesses 282, 284 of the fabric, the effective pore size of the device may be significantly reduced even at these locations.

[0063] The device 250 may also be provided with tethers 290 for collapsing the basket 270 during retraction. The basket may include four independent tether wires, each of which extends proximally from the proximal lip 286 of the deployed basket. In a preferred embodiment, though, the four tether wires illustrated in the drawings are actually formed of two longer wires, with each wire extending peripherally about a portion of the proximal lip of the basket. These tether wires may be intertwined with the wires of the metal fabric to keep the tethers in place during use. When the tethers are retracted or drawn down toward the guidewire, the wires extending along the proximal lip of the basket will tend to act as drawstrings, drawing the proximal end of the basket radially inwardly toward the guidewire. This will tend to close the basket and entrap any material caught in the cavity 288 of the basket during use so that the basket can be retracted, as detailed below.

[0064] The tether wires 290 may extend along much of the length of the guidewire so that they will extend outside the patient's body during use of the device 250. When it is desired to collapse the basket for retrieval, the operator can simply hold the guidewire 260 steady and retract the tethers with respect to the guidewire. This can tend to be relatively cumbersome, though, and may be too difficult to effectively accomplish without breaking the tethers if the device is deployed at a selective site reached by a tortuous path, such as in the brain.

[0065] Accordingly, in the preferred embodiment shown in Figures 5A and 5B, the tethers 290 are attached to the guidewire 260 at a position spaced proximally of the basket. The tethers may, for example, be attached to a metal strap 292 or the like and this strap 292 may be affixed to the shaft of the guidewire. When it is desired to close the proximal end of the basket for retraction, an external catheter (not shown) can be urged distally toward the basket 270. When the catheter encounters the radially extending tethers, the distal end of the catheter will tend to draw the tethers toward the guidewire as the catheter is advanced, which will, in turn, tend to draw the proximal end of the basket closed.

[0066] Figures 6A and 6B illustrate an alternative em-

bodiment of the device shown in Figures 5A and 5B, with Figure 6A showing the device collapsed in a catheter C for deployment and Figure 6B showing the device in its deployed configuration. In the embodiment shown in Figures 6A and 6B, the basket 270 is formed substantially the same as outlined above in connection with Figures 5A and 5B. In the embodiment of Figures 6, though, the distal band 272 is affixed to the guidewire 260' at the distal tip of the guidewire. The guidewire 260' is of the type referred to in the art as a "movable core" guidewire. In such guidewires, a core wire 265 is received within the lumen of a helically wound wire coil 266 and the core wire 265 extends distally beyond the distal end of the coil 266. A thin, elongate safety wire 268 may extend along the entire lumen of the coil 266 and the distal end of the safety wire may be attached to the distal end of the coil to prevent loss of a segment of the coil if the coil should break.

[0067] In the embodiment of Figures 5, the proximal ends of the tethers 290 are attached to a metal strap 292 which is itself attached to the shaft of the guidewire 260. In the present embodiment, the tethers are not attached to the core wire 265 itself. Instead, the tethers are attached to the coil 266 of the guidewire. The tethers may be attached to the coil by any suitable means, such as by means of laser spot welding, soldering or brazing. The tethers 290 may be attached to the coil 266 at virtually any spot along the length of the coil. As illustrated in these drawings, for example, the tethers may be attached to the coil adjacent the coil's distal end. However, if so desired the tethers may be attached to the coil at a location space more proximally from the basket 270.

[0068] An external catheter such as that referred to in the discussion of Figures 5A, but not shown in those drawings, is illustrated in Figures 6A and 6B. Once the basket 270 is deployed in a patient's vessel to substantially reach the expanded configuration shown in Figure 6B and the basket has performed its intended filtration function, the external catheter C can be urged distally toward the basket 270. As this catheter is urged forward, the tethers will tend to be drawn into the distal end of the catheter, which is substantially narrower than the proximal lip 286 of the basket. This will tend to draw the tethers down toward the guidewire and help close the basket, as explained above.

[0069] Figures 7-9 illustrate yet another alternative embodiment of a vascular trap in accordance with the present invention. This vascular trap 300 includes a basket 320 received over a guidewire 310. In most respects, the basket 320 is directly analogous to the basket 270 illustrated in Figures 5 and 6. The basket 320 includes a proximal band 322 and a distal band 324. As in the embodiment of Figures 6A and 6B, the distal band may be attached to the guidewire adjacent its distal end. If so desired, though, a structure such as is shown in Figures 5, wherein the guidewire extends distally beyond the basket, could instead be used.

[0070] As best seen in its collapsed state (shown in

Figure 6A), the basket includes a distal segment 325 and a proximal segment 326, with the distal end of the distal segment being attached to the distal band 324 and the proximal end of the proximal segment being attached to the proximal band 322. When the basket 320 is in its expanded configuration (shown in Figure 6B), the proximal segment 326 is received within the distal segment 325, defining a proximal lip 328 at the proximal edge of the device. The wall of the basket thus formed also includes a cavity 329 for trapping solids entrained in a fluid, such as emboli in a patient's blood stream.

[0071] The basket 320 of Figures 7-9 is also shaped a little bit differently than the basket 270 of the previous drawings. The primary difference between these two baskets is that the basket 320 is a little bit shorter along its axis than the basket 270. This different basket shape is simply intended to illustrate that the basket of a vascular trap in accordance with the invention can have any of a wide variety of shapes and no particular significance should be attached to the slightly different shapes shown in the various drawings.

[0072] In the vascular traps 250 and 250' of Figures 5 and 6, respectively, tethers were used to draw down the proximal end of the basket 270 to close the basket for retraction. In the embodiment shown in Figures 7-9, though, the trap 300 includes a basket cover 340 positioned proximally of the basket 320. The basket cover may also be formed of a metallic tubular braid and is also adapted to be collapsed to lay generally along the outer surface of the guidewire 310. The cover 340 is not directly affixed to the guidewire at any point, though, but is instead intended to be slidable along the guidewire. As best seen in Figures 7 and 8 wherein the cover is in its collapsed state, the cover 340 includes a distal hypotube 342 and a proximal control hypotube 344, with the distal hypotube being attached to the distal end of the cover 340 and the proximal control hypotube 344 being attached to the proximal end of the cover.

[0073] The cover 340 is shown in its deployed, expanded configuration in Figure 9. As shown in that figure, the cover has a similar structure to that of the basket 320, but is oriented to be open distally rather than proximally, as is the basket. As best seen in Figures 7 and 8 wherein the cover is in its collapsed state, the cover has a distal segment 352 and a proximal segment 354. When the cover is deployed by urging it distally out of the distal end of the deployment catheter C, the cover 340 will tend to resiliently return to its expanded configuration and the distal hypotube 342 will slide axially proximally along the guidewire toward the proximal control hypotube 344. This will invert the collapsed cover so that the distal section 352 is generally received within the proximal section 354, defining a distal lip 358 of the cover.

[0074] The proximal control hypotube 344 may extend along a substantial portion of the length of the catheter 310 so that it extends out of the patient's body when the device 300 is in place. By grasping the control hy-

potube and moving it relative to the guidewire 310, an operator can control the position of the cover 340 with respect to the basket 320, which is affixed to the guidewires. As explained in more detail below in connection with the use of the device 300, once the basket has been deployed and has been used to filter objects entrained in the fluid (e.g. emboli in blood), the cover 340 may be deployed and the trap may be drawn proximally toward the cover by moving the guidewire proximally with respect to the control hypotube 344.

[0075] The inner diameter of the distal lip 358 of the cover is desirably slightly larger than the outer diameter of the proximal lip 328 of the basket. Hence, when the basket is drawn proximally toward the cover it will be substantially enclosed therein. The cover will therefore tend to trap any emboli (not shown) or other particulate matter retained within the cavity 330 of the basket. A retrieval sheath S may then be urged distally to engage the outer surface of the cover 340. This will tend to cause the cover to collapse about the basket, tightly engaging the outer surface of the basket. This somewhat collapsed structure can then be withdrawn from the patient's channel and removed from the patient's body. By enclosing the basket within the cover, the likelihood of any filtered debris within the basket being lost as the basket is retrieved will be substantially eliminated.

[0076] The guidewire and the metal fabric can be of any diameter suitable for the intended application of the vascular trap 250, 250' or 300. In a preferred embodiment, the guidewire is between about 0.014" (about 0.36 mm) and about 0.038" (about 0.97 mm) in diameter and the wires of the metal fabric used to form the basket (and the cover 340, if a cover is included) are between about 0.002" (about 0.05 mm) and about 0.006" (about 0.15 mm). The thickness of the metal bands (272, 274 or 322, 324) also is desirably in the range of about 0.002" to 0.006" (about 0.05 to 0.15 mm).

[0077] In one particularly preferred embodiment intended to be used in narrower vessels such as those encountered in cerebral and coronary applications, the guidewire has an outer diameter of about 0.014" (about 0.36 mm) and the wires of the metal fabric are about 0.002" (about 0.05 mm) in diameter. The metal bands in this embodiment may also have a thickness of about 0.002" (about 0.05 mm) so that they will not be substantially wider than the collapsed basket. When the device is collapsed for deployment through a catheter, it will have an outer diameter of about 0.018" (about 0.46 mm), permitting the device to be used with catheters and other instruments adapted for use with a 0.018" (about 0.46 mm) guidewire.

[0078] Figure 10 illustrates one embodiment of a molding element 370 which may be used in making a basket 270. Although the basket 320 and cover 340 of the trap 300 are shaped somewhat differently, an analogous molding element can be used for these portions of the trap 300 as well by simply modifying some of the dimensions of the molding element 370, but retaining

the basic shape and structure of the molding element. It also should be understood that the molding element 370 is merely one possible molding element for forming a shape such as that of the basket 270 and that any one of a variety of different molding elements will be apparent to those skilled in the art.

[0079] The molding element 370 has an outer molding section 372 defining a curved inner surface 374 and an inner molding section 376 having an outer surface 378 substantially the same shape as the curved inner surface 374 of the outer molding section. The inner molding section 376 should be sized to be received within the outer molding section, with a piece of the metal fabric (not shown) being disposed between the inner and outer molding sections. In a preferred embodiment, the inner surface 374 of the outer molding element and the outer surface 378 of the inner molding section each include a recess (375 and 379, respectively) for receiving an end of the braid. The molding surface of this molding element 370, to which the fabric will generally conform, can be considered to include both the inner surface 374 of the outer molding section and the outer surface 378 of the inner molding section.

[0080] In use, the two molding sections 372, 376 are spaced apart from one another and a length of a tubular braid of metal fabric (not shown in Figure 10) is disposed between these molding sections. Optimally, one end of the fabric is placed in the recess 375 of the outer molding section and the other end of the fabric is placed in the recess 379 in the inner molding section. The inner and outer molding sections can then be urged generally toward one another. As the ends of the wire approach one another, the tubular braid will tend to invert upon itself and a surface of the tubular braid will generally conform to either the inner surface 374 of the outer molding section or the outer surface 378 of the inner molding section, arriving at a shape analogous to that of the basket 270 of the traps 250, 250'. The two molding sections can then be locked in place with respect to one another and the metal fabric may be heat treated to set the wires in this deformed configuration.

[0081] Medical devices outlined above have a preset expanded configuration and a collapsed configuration which allows the device to be passed through a catheter. The expanded configuration is generally defined by the shape of the medical fabric when it is deformed to generally conform to the molding surface of the molding element. Heat treating the metal fabric substantially sets the shapes of the wire strands in the reoriented relative positions when the fabric conforms to the molding surface. When the metal fabric is then removed from the molding element, the fabric may define a medical device in its preset expanded configuration.

[0082] The medical device can be collapsed into its collapsed configuration and inserted into the lumen of the catheter. The collapsed configuration of the device may be of any shape suitable for easy passage through the lumen of a catheter and proper deployment out the

distal end of the catheter.

[0083] Once the medical device is collapsed and inserted into the catheter, it may be urged along the lumen of the catheter toward the distal end of the catheter. This may be accomplished by using a guidewire or the like to abut against the device and urge it along the catheter. When the device begins to exit the distal end of the catheter, which is positioned adjacent the desired treatment site, it will tend to resiliently return substantially entirely to its preset expanded configuration. Superelastic alloys, such as nitinol, are particularly useful in this application because of their ability to readily return to a particular configuration after being elastically deformed to a great extent. Hence, simply urging the medical device out of the distal end of the catheter tend to properly deploy the device at the treatment site.

[0084] Although the device will tend to resiliently return to its initial expanded configuration (i.e. its shape prior to being collapsed for passage through the catheter), it should be understood that it may not always return entirely to that shape.

[0085] If such a device is deployed in a vessel having a small lumen, the lumen will prevent the device from completely returning to its expanded configuration. Nonetheless, the device would be properly deployed because it would engage the inner wall of the lumen to seat the device therein, as detailed above.

[0086] The devices 250, 250' and 300 are advantageously deployed for use in conjunction with another medical device and will most frequently be retracted from the patient's body after use.

[0087] For example, any one of these devices are suitable for use in conjunction with a balloon angioplasty procedure. In such procedures, catheters having inflatable balloons at their ends, referred to as balloon catheters, are positioned within a blood vessel so that the balloon is positioned within a stenosis. These balloons are positioned by tracking the balloon catheter along a guidewire or the like; the balloons typically have a central bore therethrough. Once the balloon is properly positioned, it is inflated and urges radially outwardly against the stenosis. This will tend to squeeze the stenosis against the walls of the vessel, improving patency of the vessel.

[0088] When the stenosis is treated in this fashion, though, there is a risk that some debris will break free and enter the blood flowing through the vessel. If left unchecked, this embolus can drift downstream and embolize a distal portion of the vessel. Depending on where the embolus comes to rest, the embolization can result in significant tissue or organ damage. This risk is particularly acute in cardiac and coronary applications because the embolization can result in a myocardial infarction or heart attack, and in neurovascular and interventional radiological procedures the embolization can lead to a stroke or damage to brain tissue.

[0089] In order to prevent, or at least substantially limit, such embolization, a vascular trap 250, 250' or 300

of the invention can be used with the balloon catheter. The device should be sized to permit it to be passed through the lumen of the particular balloon catheter to be used in the angioplasty.

5 [0090] In one embodiment of a method for using such a vascular trap, the trap is deployed first. The basket (270 or 320) of the trap will be guided to a position located downstream of the desired treatment site through an introduction catheter (e.g. the catheter C in Figures 6-9). The basket is then urged distally beyond the end of the catheter, which will permit the basket to resiliently substantially return to its expanded configuration from its collapsed configuration within the catheter. Once the trap is in place, the balloon catheter can be exchanged for the introduction catheter, and the balloon catheter can track the guidewire (260 or 310) of the vascular trap. The balloon can then be positioned within the stenosis and expanded, as outlined above. Once the angioplasty has been completed, the balloon can be deflated again and withdrawn proximally out of the patient.

20 [0091] In an alternative embodiment of the present method, the balloon catheter can be used to perform the same function as performed by the introduction catheter in the preceding embodiment. In this embodiment, the balloon catheter is positioned in the patient's vessel so that the distal end of the balloon catheter is located downstream of the stenosis. The vascular trap (250, 250' or 300) of the invention is then passed through the lumen of the balloon catheter and the basket is urged out of the distal end of the catheter. The basket will resiliently substantially return to its preferred expanded configuration, whereupon the balloon catheter can be retracted along the shaft of the device's guidewire until the balloon is properly positioned within the stenosis.

35 [0092] If so desired, the balloon catheter can instead be provided with a length of standard catheter extending distally beyond the distal end of the balloon. The balloon can then be positioned within the stenosis and the basket can be urged out of the distal end of the distal extension of the catheter. In such an embodiment, the length of the distal extension of the catheter should be sufficient to properly position the basket with respect to the balloon when the basket exits the distal end of the catheter. This will eliminate the need to perform the separate step of retracting the balloon into position within the stenosis after the basket is deployed. The balloon can then be expanded, deflated and withdrawn as described above.

45 [0093] Much the same procedure can be used to deploy a vascular trap of the invention for use in an atherectomy procedure. In such procedures, a cutting head is positioned at the distal end of an elongate, hollow shaft and the cutting head has a bore extending therethrough. The trap can be deployed in either of the methods outlined above, but it is anticipated that in most instances the first procedure will be used, i.e. the basket will be deployed with an introduction catheter, which will be removed so that the cutting device can be guided

over the guidewire of the vascular trap. It should also be understood that the device 250, 250' and 300 could also be used in other medical procedures in other bodily channels besides a patient's vascular system.

[0094] Since the trap is positioned downstream of the stenosis, any debris released during the procedure will tend to drift distally toward the basket and be caught therein. In order to prevent any emboli from simply floating past the trap, it is preferred that the proximal lip (288 or 328) of the basket be at least as large as the lumen of the vessel. In a preferred embodiment, the natural dimension of the proximal lip (i.e. where the basket has fully returned to its expanded configuration) is somewhat greater than the vessel's inner diameter so that the basket will firmly engage the wall of the vessel.

[0095] The method of retracting the basket will depend on which embodiment of the vascular trap is used, namely whether or not the device includes a cover 340. The device 250 or 250' of Figures 5 or 6, respectively, do not include such a cover. However, they do include tethers 290 which extend proximally from the proximal lip 288 of the basket to an attachment to the guidewire. In either of these embodiments, a retrieval catheter can be introduced over the guidewire and urged distally toward the basket. As explained above in connection with Figures 5 and 6, this will tend to draw the tethers down toward the guidewire, effectively closing the proximal end of the basket 270. Once the basket is sufficiently closed, such as when the proximal lip of the basket engages the distal tip of the retrieval catheter, the catheter and the vascular trap can be retracted together from the patient's body. By substantially closing the proximal end of the basket in such a fashion, any emboli which are captured in the basket when it is deployed can be retained within the basket until it is removed from the patient's body.

[0096] If so desired, a balloon catheter or like device can instead be used, with the balloon catheter being used to draw down the tethers 290 and collapse the basket. The vascular trap can then be withdrawn with the balloon catheter rather than having to separately introduce a removal catheter to remove the trap.

[0097] In withdrawing the embodiment illustrated in Figures 7-9, the cover 340 is positioned over the proximal lip of the basket before the vascular trap 300 is retracted. Once the medical procedure is completed and any debris has been captured in the basket, the cover 340 is allowed to resiliently substantially return to its expanded configuration. Once it is deployed proximally of the basket, the basket 320 can be drawn proximally toward the cover 340 until it engages or is received within the cover, as noted above in connection with Figure 9.

[0098] In actuality, the cover 340 may be unable to return to its full expanded configuration due to the confines of the vessel in which it is deployed. As explained previously, the cover 340 is desirably larger than the basket 320 so that the basket can be received within the cover. However, the basket is optimally sized to engage

the walls of the vessel to prevent the unwanted passage of emboli or other debris around the edges of the basket. Accordingly, the distal lip 358 of the cover will engage the wall of the channel before it expands to its full size.

5 The walls of most bodily channels, such as blood vessels, tend to be somewhat elastic, though. The cover 340 will therefore tend to urge harder against the wall of the vessel than the smaller basket and may stretch the vessel a little bit more than will the basket. In this fashion, the cover may still be able to expand to a dimension large enough to permit the basket to be received in the cavity 356 of the cover. If not, the distal lip 358 of the cover can simply be brought into close engagement with the proximal lip 328 of the basket to generally seal the basket.

10 [0099] Once the cover 340 is brought into engagement with the basket 320, whether by receiving the basket within the cover or, less preferably, by engaging the lips 358, 328 of the cover and the basket, the device can be withdrawn proximally from the patient's vascular system. The cover will tend to prevent any emboli caught in the basket during deployment from being inadvertently lost during withdrawal.

15 [0100] The vascular traps 250, 250' and 300 of the present invention therefore have distinct advantages over other vascular traps or filters currently known in the art. As explained above, most prior art traps are difficult and expensive to form and cannot be readily collapsed for retrieval. The present method for making the vascular traps 250, 250' and 300 which is both relatively inexpensive and less labor intensive, generally resulting in a more consistent product than prior art hand-forming methods. Furthermore, the structure of the device and the methods outlined above for removing the device will fairly reliably prevent the inadvertent dumping of trapped emboli back into the bloodstream while the device is being removed. Since most prior art traps and filters are much more difficult to use and are more likely to dump filtered debris back into the bloodstream, the present invention can be substantially safer than these prior art systems.

Claims

- 45 1. A trap for trapping particulate material entrained in a fluid within a channel of a patient's body, comprising a guidewire having a distal end and a basket (270) carried by the guidewire (260) adjacent the distal end, the basket (270) being adapted to strain the particulate material from fluid passing there-through and comprising a metal fabric having first and second ends, at least one end of the fabric being adapted to slide along the guidewire, the metal fabric having a collapsed configuration wherein the first and second ends are spaced from one another a first distance along the guidewire and the metal fabric has a first diameter, and an expanded config-

uration wherein the first and second ends are spaced a second, shorter distance along the guidewire and the metal fabric has a second diameter, the first diameter being less than the second diameter.

2. The trap of Claim 1, wherein the first end is affixed to the guidewire (260).
3. The trap of either preceding claim, wherein the metal fabric is resilient and the second end will resiliently slide toward the first end to define a particle trapping screen when the fabric is not constrained.
4. The trap of any preceding claim, wherein a first length of the metal fabric extending proximally from the first end defines a distal surface of the screen and a second length of the metal fabric extending distally from the second end of the fabric defines a proximal surface of the screen.
5. The trap of Claim 4, wherein the screen is generally dome-shaped and the second length of the fabric is received within the first length of the fabric.
6. The trap of Claim 4 or Claim 5, wherein a central portion of the metal fabric defines a proximally-facing lip of the screen.
7. The trap of any preceding claim further comprising a tether (290) extending from the screen to the guidewire, the tether (290) being attached at one end to the guidewire (260).
8. The trap of Claim 7 wherein the screen has a periphery, the tether (290) comprising a wire attached at each end to the guidewire and extending about the periphery of the screen such that when the tether is drawn inwardly toward the guidewire it will act as a drawstring to collapse the periphery of the screen toward the guidewire.
9. The trap of Claim 1 or Claim 2 further comprising a cover (340) formed of a metal fabric, the cover being slidable along the guidewire (260) from a first position spaced proximally of the screen toward a second position adjacent the screen.
10. The trap of Claim 9 wherein the cover has two ends, the cover being disposed adjacent the outer surface of the guidewire (260) when one end is spaced proximally of the other end and extending generally outwardly of the guidewire to a diameter at least as great as an outer diameter of the screen when one end of the cover is slid nearer the other end.
11. The trap of Claim 9 or Claim 10 wherein the screen is generally dome-shaped and includes a proximal-

ly-facing lip, the cover in an expanded configuration defining a recess sized to receive the lip of the screen.

- 5 12. The trap of Claim 11 wherein the screen has an outer diameter and the cover has an inner diameter greater than the outer diameter of the screen.
- 10 13. The trap of any preceding claim in which the metal fabric in its expanded configuration including pores therein of no more than 1.0 mm in size and being adapted to strain the particulate material from fluid passing through the fabric.
- 15 14. The trap of any preceding claim in which the second end is resiliently biased toward the first end to define a particle trapping screen when the fabric is not constrained.

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Patentansprüche

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1. Eine Sammelvorrichtung zum Sammeln partikelförmigen Materials, welches in einer Flüssigkeit innerhalb eines Kanals eines Patientenkörpers enthalten ist, umfassend einen Führungsdraht mit einem distalen Ende und einem Korb (270), welcher von dem Führungsdraht (260) benachbart zum distalen Ende getragen wird, wobei der Korb (270) ausgebildet ist, um das partikelförmige Material von dem Fluid, welches ihn durchläuft, zu filtern und ein Metallgewebe umfasst, welches erste und zweite Enden aufweist, wobei wenigstens ein Ende des Gewebes ausgebildet ist, entlang des Führungsdrahtes zu gleiten und das Metallgewebe eine kollabierbare Anordnung hat, bei der die ersten und zweiten Enden voneinander eine erste Distanz entlang des Führungsdrahtes beabstandet sind und das Metallgewebe einen ersten Durchmesser hat, und eine expandierte Anordnung, bei der die ersten und zweiten Enden um eine zweite, kürzere Distanz entlang des Führungsdrahtes beabstandet sind und das Metallgewebe einen zweiten Durchmesser hat und der erste Durchmesser kleiner ist als der zweite Durchmesser.
2. Sammelvorrichtung nach Anspruch 1, bei der das erste Ende an dem Führungsdraht (260) befestigt ist.
3. Sammelvorrichtung nach einem der vorhergehenden Ansprüche, bei dem das Metallgewebe elastisch ist und das zweite Ende elastisch in Richtung des ersten Endes gleitet, um einen Partikelaufnahmeschirm zu bilden, wenn das Gewebe nicht komprimiert ist.
4. Sammelvorrichtung nach einem der vorhergehenden

den Ansprüche, bei der eine erste, sich proximal von dem ersten Ende erstreckende Länge des Metallgewebes eine distale Oberfläche des Schirms bildet und eine zweite, sich distal von dem zweiten Ende des Gewebes erstreckende Länge des Metallgewebes eine proximale Oberfläche des Schirms bildet.

5. Sammelvorrichtung nach Anspruch 4, bei der der Schirm allgemein kuppelförmig ist und die zweite Länge des Gewebes innerhalb der ersten Länge des Gewebes aufgenommen wird. 10
6. Sammelvorrichtung nach Anspruch 4 oder 5, bei der ein zentraler Abschnitt des Metallgewebes eine nach proximal weisende Lippe des Schirmes bildet. 15
7. Sammelvorrichtung nach einem der vorhergehenden Ansprüche, weiterhin umfassend ein Halteseil (290), welches sich von dem Schirm zu dem Führungsdraht erstreckt und an einem Ende des Führungsdrahtes (260) befestigt ist. 20
8. Sammelvorrichtung nach Anspruch 7, bei der der Schirm einen Umfang hat und das Halteseil (290) einen Draht umfasst, der an jedem Ende an dem Führungsdraht befestigt ist und sich um den Umfang des Schirms solcher Art erstreckt, dass, wenn das Halteseil einwärts in Richtung des Führungsdrahtes gezogen wird, er als Zugschlinge zum Kollabieren des Umfangs des Schirms in Richtung des Führungsdrahtes wirkt. 30
9. Sammelvorrichtung nach Anspruch 1 oder 2, weiterhin umfassend eine auf dem Metallgewebe ausgebildete Abdeckung (340), welche gleitend ist entlang des Führungsdrahtes (260) von einer ersten Position, welche von dem Schirm proximal beabstandet ist, in Richtung einer zweiten Position, welche dem Schirm benachbart ist. 35
10. Sammelvorrichtung nach Anspruch 9, bei der die Abdeckung zwei Enden hat und die Abdeckung benachbart zur äußeren Oberfläche des Führungsdrahtes (260) angeordnet ist, wenn ein Ende proximal von dem anderen beabstandet ist und die Abdeckung sich allgemein auswärts von dem Führungsdraht zu einem Durchmesser erstreckt, welcher wenigstens so groß ist wie der äußere Durchmesser des Schirms, wenn ein Ende der Abdeckung näher zu dem anderen Ende geglitten ist. 40
11. Sammelvorrichtung nach Anspruch 9 oder 10, bei der der Schirm allgemein kuppelförmig ist und eine nach proximal weisende Lippe beinhaltet und die Abdeckung in einer expandierten Anordnung eine Vertiefung definiert, welche bemessen ist, um die Lippe des Schirms aufzunehmen. 45

12. Sammelvorrichtung nach Anspruch 11, bei der der Schirm einen äußeren Durchmesser hat und die Abdeckung einen inneren Durchmesser hat, welcher größer ist als der äußere Durchmesser des Schirms. 5

13. Sammelvorrichtung nach einem der vorhergehenden Ansprüche, bei der das Metallgewebe in seiner expandierten Anordnung Poren darin beinhaltet, welche nicht größer als 1,0 mm sind und welche ausgebildet sind, das partikelförmige Material von dem Fluid, welches durch das Gewebe läuft, zu filtern. 10

14. Sammelvorrichtung nach einem der vorhergehenden Ansprüche, bei der das zweite Ende beweglich gegenüber dem ersten Ende vorgespannt ist, um einen Partikelsammelschirm zu definieren, wenn das Gewebe nicht komprimiert ist. 15

Revendications

1. Un piège destiné à piéger de la matière particulaire entraînée dans un fluide à l'intérieur d'un canal du corps d'un patient, comportant un fil guide avec une extrémité distale et un panier (270) placé sur le fil guide (260) et adjacent à l'extrémité distale, le panier (270) pouvant contraindre la matière particulaire provenant du fluide à passer par le fil guide et comportant un tissu métallique ayant une première et seconde extrémité, au moins une extrémité du tissu étant apte à glisser le long du fil guide, le tissu métallique ayant une configuration écrasée dans laquelle la première et la seconde extrémité sont espacées l'une de l'autre d'une première distance le long du fil guide et le tissu métallique a un premier diamètre, et une configuration expansée dans laquelle la première et la seconde extrémités sont espacées d'une seconde distance plus courte, le long du fil guide et le tissu métallique a un second diamètre, le premier diamètre étant plus petit que le second diamètre. 20

2. Le piège de la revendication 1 dans lequel la première extrémité est fixée sur le fil guide (260). 25

3. Le piège de l'une quelconque des revendications précédentes dans lequel le tissu métallique est flexible et la seconde extrémité glisse de manière flexible vers la première extrémité pour former un écran apte à piéger les particules lorsque le tissu n'est pas ramassé sur lui-même. 30

4. Le piège selon l'une quelconque des revendications précédentes dans lequel une première longueur du tissu métallique s'étendant proximement à partir de la première extrémité définit une surface distale 35

de l'écran et une seconde longueur du tissu métallique s'étendant distalement à partir de la seconde extrémité définit une surface proximale de l'écran.

d'une taille non supérieure à 1,0 mm et est apte à contraindre la matière particulaire provenant du fluide à passer par le tissu.

5. Le piège de la revendication 4 dans lequel l'écran est généralement en forme de dôme et la seconde longueur du tissu est contenue dans la première longueur du tissu.
6. Le piège de la revendication 4 ou 5 dans lequel une portion centrale du tissu métallique forme une lèvre à face proximale de l'écran.
7. Le piège de l'une quelconque des revendications précédentes comportant en outre une attache (290) s'étendant de l'écran vers le fil guide, l'attache (290) étant reliée à une extrémité du fil guide (260)
8. Le piège de la revendication 7 dans lequel l'écran a une périphérie, l'attache (290) comportant un fil attaché à chaque extrémité au fil guide et s'étendant à la périphérie de l'écran de telle sorte que lorsque l'attache est tirée vers l'intérieur en direction du fil guide, elle agit comme un cordon pour écraser la périphérie de l'écran vers le fil guide.
9. Le piège de la revendication 1 ou 2 comportant en outre un revêtement (340) constitué de tissu métallique, ce revêtement pouvant glisser le long du fil guide (260) à partir d'une première position espacée proximale de l'écran vers une seconde position adjacente à l'écran.
10. Le piège de la revendication 9 dans lequel le revêtement a deux extrémités, le revêtement étant adjacent à la surface extérieure du fil guide (260) lorsqu'une extrémité est espacée proximale de l'autre extrémité et s'étendant généralement vers l'extérieur du fil guide jusqu'à avoir un diamètre au moins aussi grand qu'un diamètre extérieur de l'écran lorsqu'une extrémité du revêtement est glissée plus près de l'autre extrémité.
11. Le piège de la revendication 9 ou 10 dans lequel l'écran possède la forme générale d'un dôme et comprend une lèvre à face proximale, le revêtement en configuration expansée formant une alvéole d'une dimension apte à recevoir la lèvre de l'écran.
12. Le piège de la revendication 11 dans lequel l'écran a un diamètre extérieur et le revêtement a un diamètre intérieur plus grand que le diamètre extérieur de l'écran.
13. Le piège de l'une quelconque des revendications précédentes dans lequel le tissu métallique comporte, dans sa configuration expansée, des pores
14. Le piège de l'une quelconque des revendications précédentes dans lequel la seconde extrémité est déformée de façon élastique vers la première extrémité pour former un écran apte à piéger les particules lorsque le tissu n'est pas contraint.

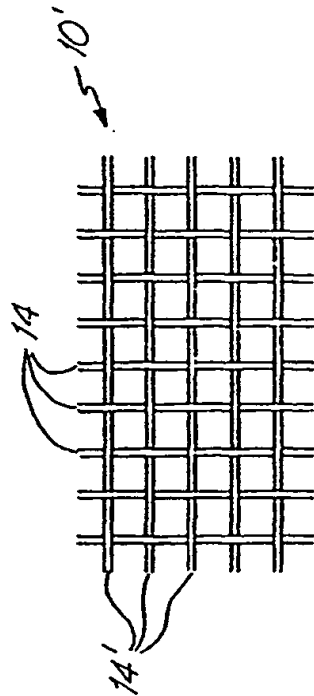


Fig. 1B

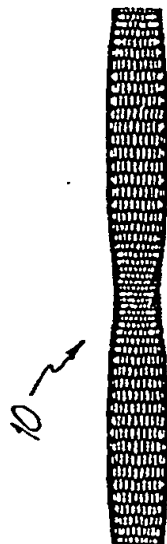
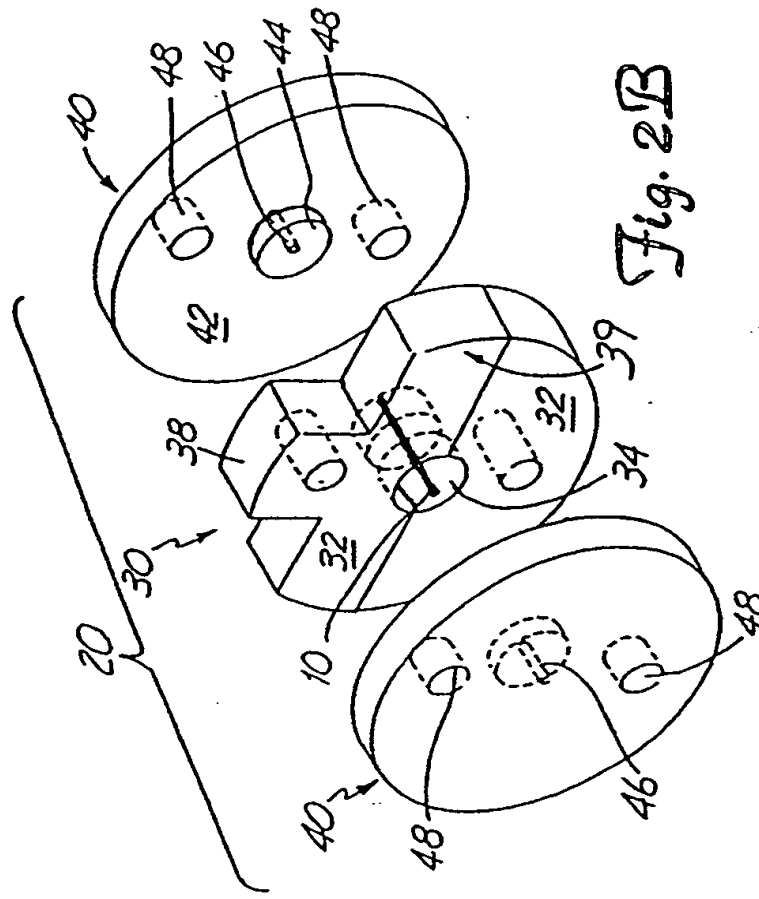
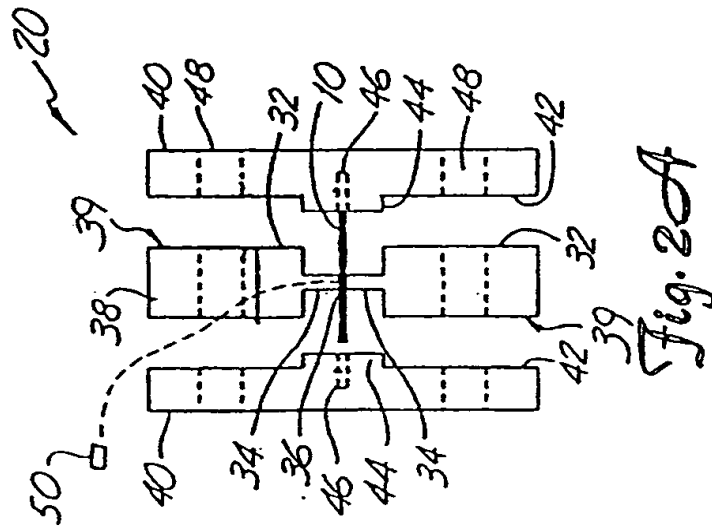


Fig. 1A



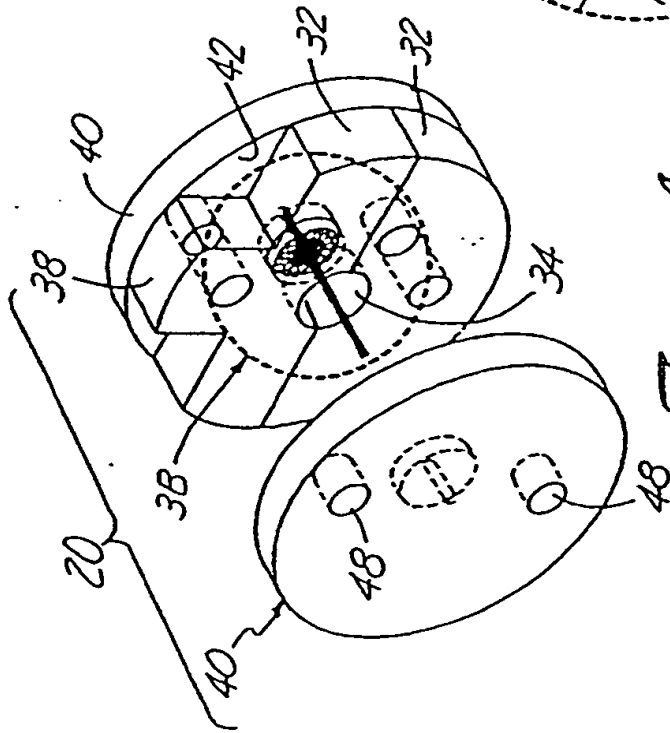


Fig. 3A

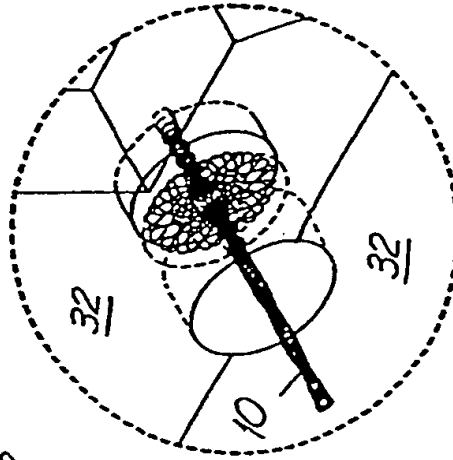


Fig. 3B

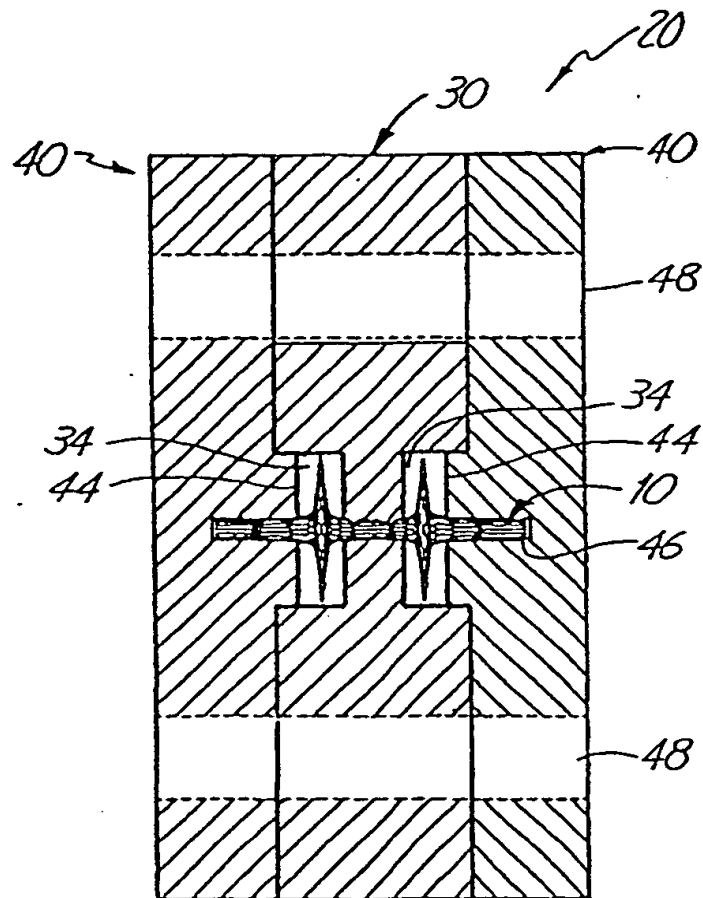


Fig. 4

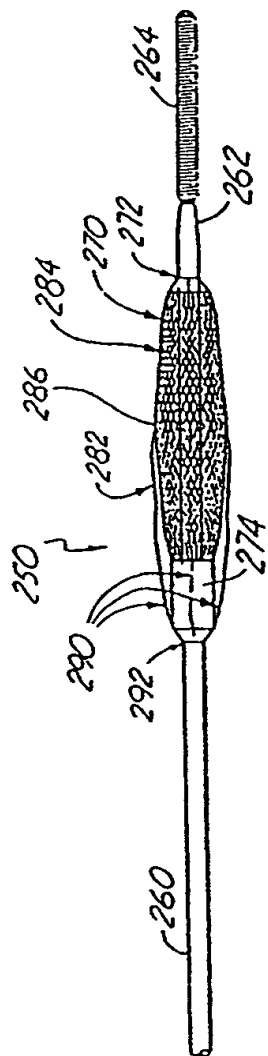


Fig. 5A

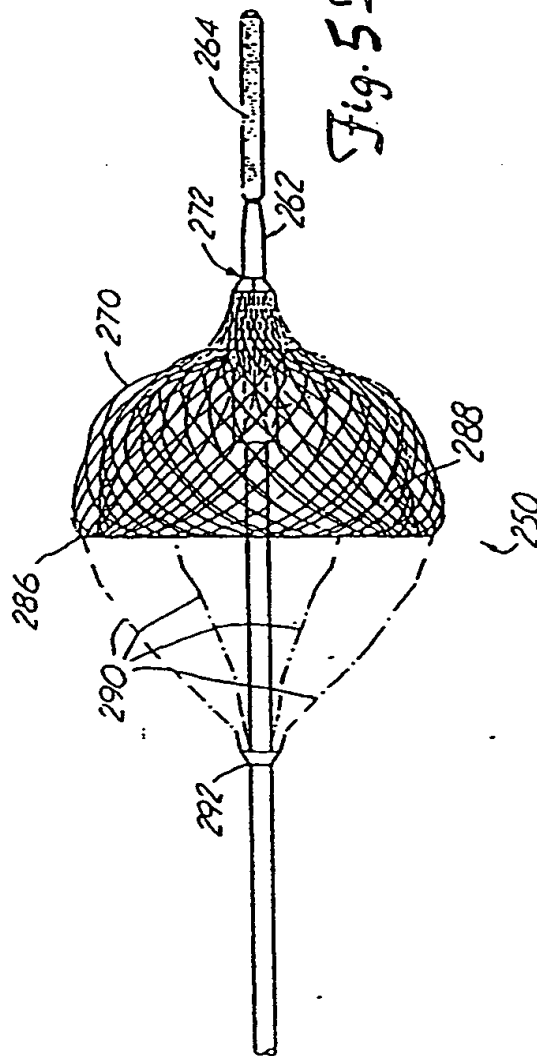
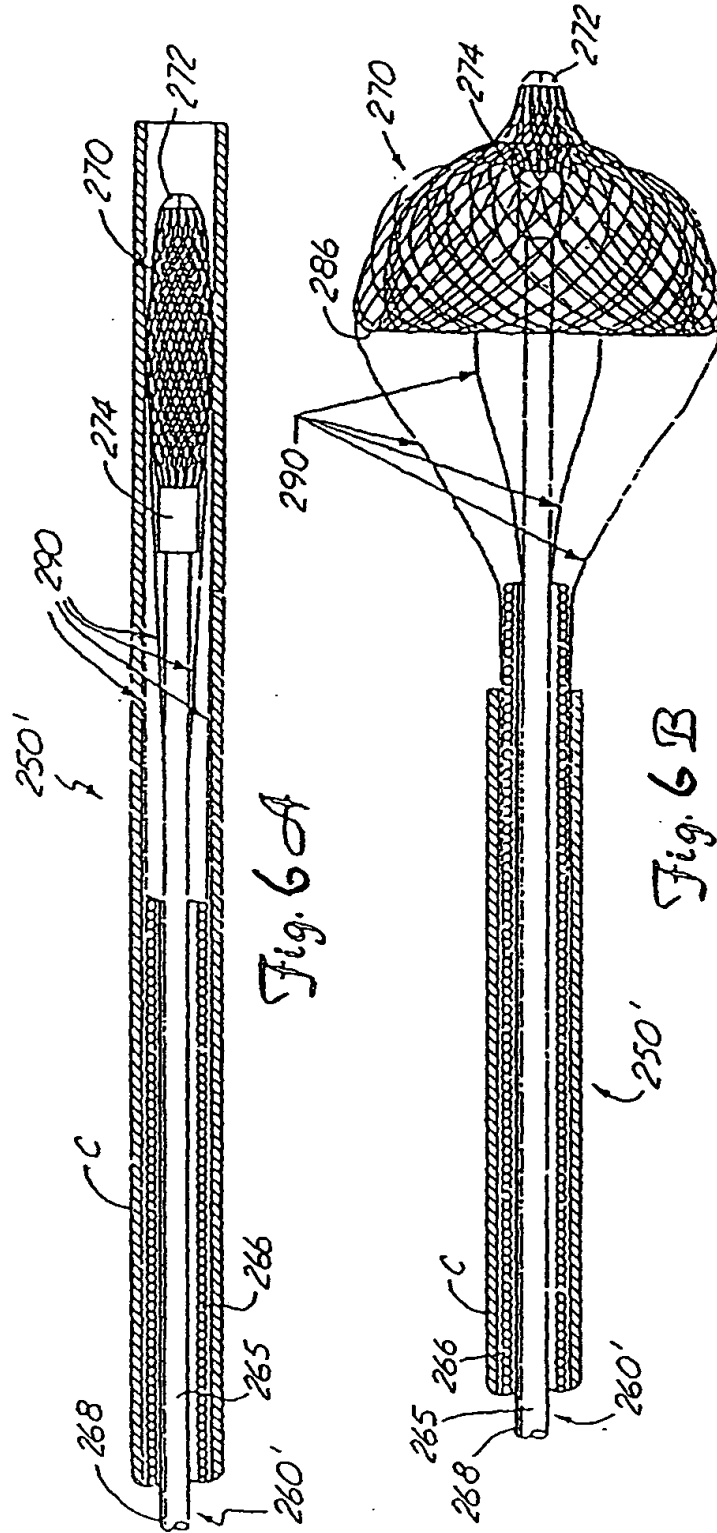
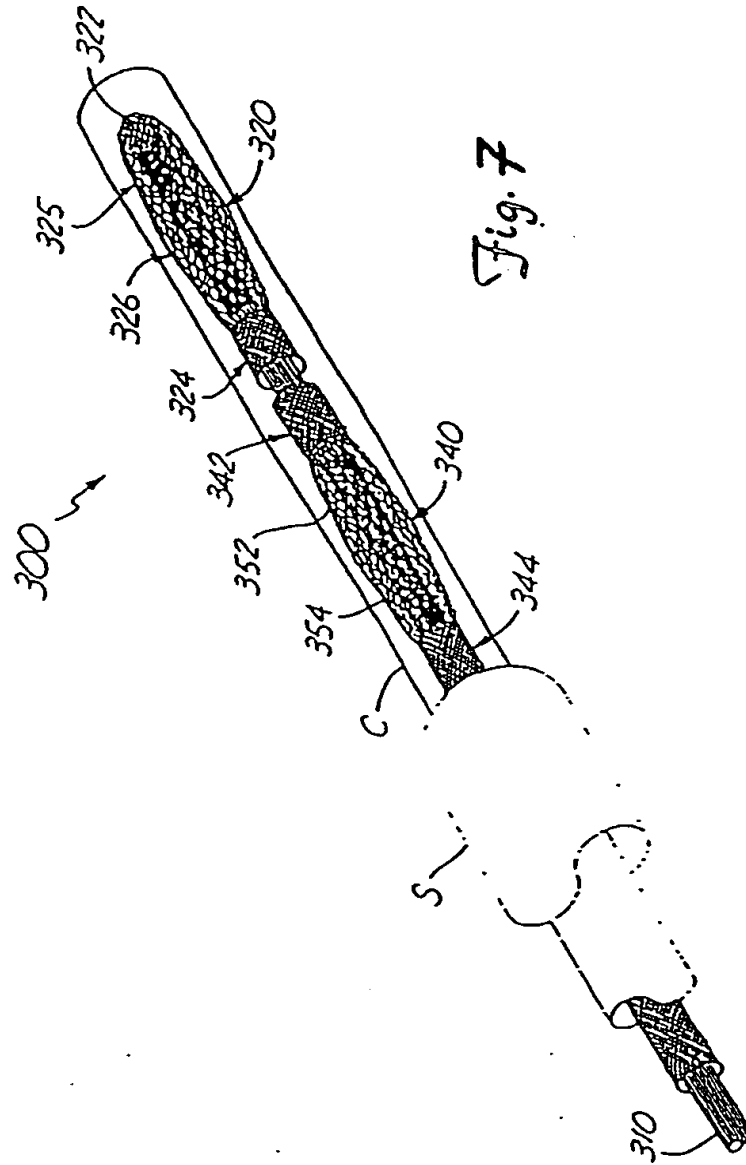


Fig. 5B





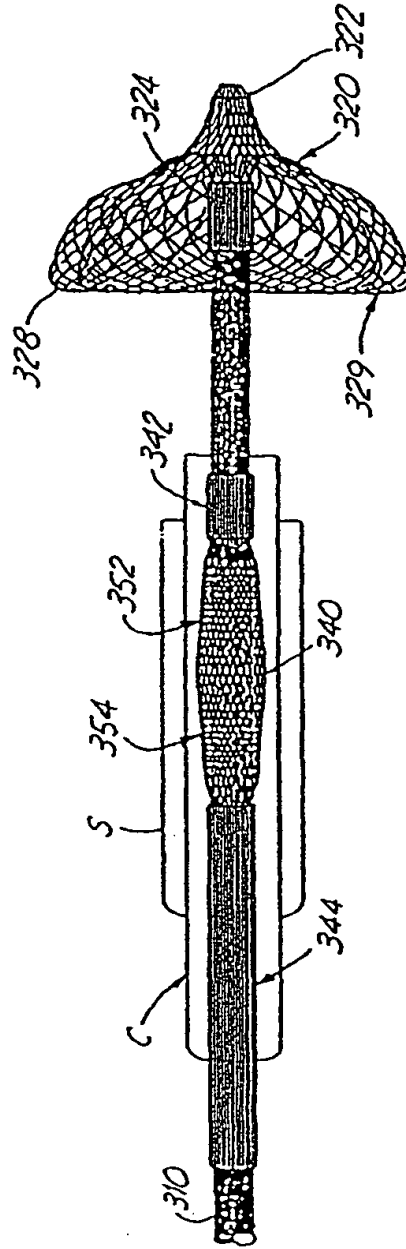


Fig. 8

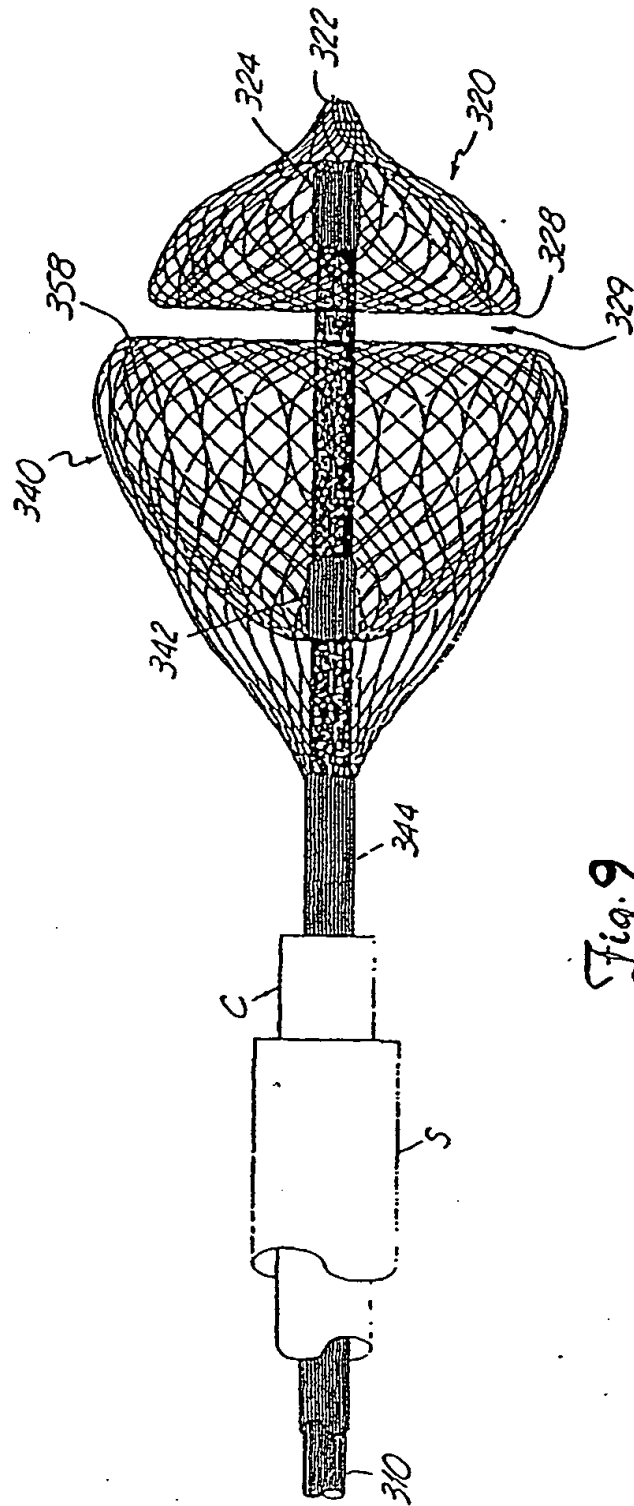


Fig. 9

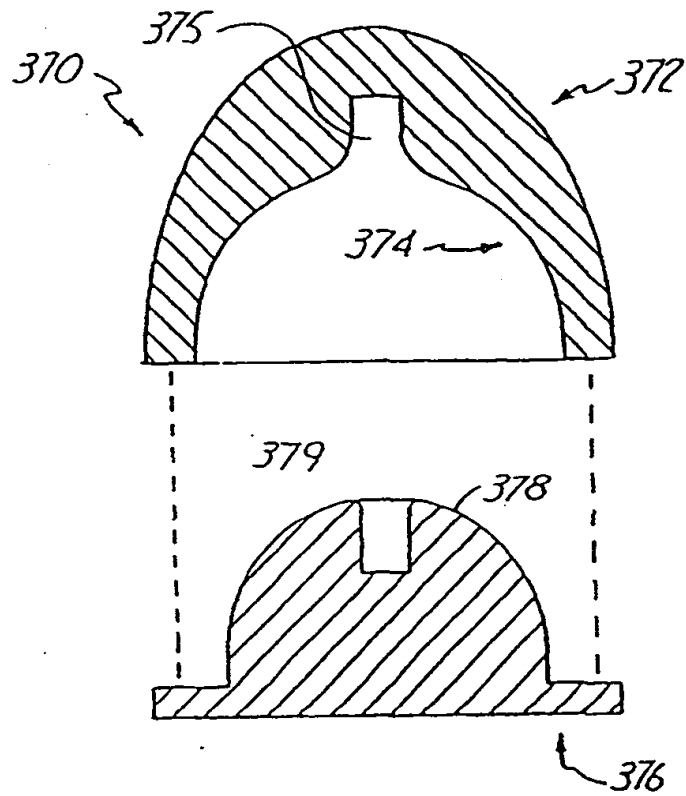


Fig. 10